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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,391	10/15/2004	Andrea Parrino	07552.0041	2102

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EXAMINER
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FRISTOE JR, JOHN K

ART UNIT	PAPER NUMBER
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3751

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/511,391

**Applicant(s)**

PARRINO ET AL.

**Examiner**

John K. Fristoe Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-11, 15-20, 26-29, 31 and 32 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 12-14, 21-25 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/13/05, 7/26/05</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statements filed on 7/13/2005 and 7/26/2005 are acknowledged by the examiner.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “lateral ports” recited in claim 30 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

*Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 6-11, 15, 18-20, 26-29, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 6,050,978 (Orr et al.). Orr et al. discloses a connection element comprising a main body (20), a fluid passage (44), a first opening (22), a second opening (31), a shut-off element (40), a fixing portion (43), an intermediate portion (42), sealing portion (41), a first operating condition (figure 3), a second operating condition (figure 5), wherein the intermediate portion (42) deforms symmetrically (figure 4), wherein the sealing portion (41) is positioned level or flush with the leading edge (figure 3) that is slightly curved, a fluid channel (35), an outer body (23), a core (30), a tubular expansion (surrounds element 31 in figure 3), a distal portion (36), a proximal portion (31), a joining portion (35), means (21) for connecting the body to an auxiliary connection (luer connector shown in figure 4), wherein the main body (10) is made of a rigid material, wherein the sealing portion (41), fixing portion (43), and intermediate portion (42) are made of an elastomeric material (col. 5, lines 51-53), and wherein the auxiliary connector has a axially-symmetric male element that opens the valve (figure 5).

Regarding the tubes connecting to the distal and proximal end of the connector and the tubes being a part of peritoneal dialysis line, luer fittings at each end of the connector are capable of being connected to any medical instrument including a tube.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,050,978 (Orr et al.) in view of U.S. Pat. No. 4,745,950 (Mathieu). Orr et al. discloses a connection element comprising a main body (20), a fluid passage (44), a first opening (22), a second opening (31), a shut-off element (40), a fixing portion (43), an intermediate portion (42), sealing portion (41), a first operating condition (figure 3), a second operating condition (figure 5), wherein the intermediate portion (42) deforms symmetrically (figure 4), wherein the sealing portion (41) is positioned level or flush with the leading edge (figure 3) that is slightly curved, a fluid channel (35), an outer body (23), a core (30), a tubular expansion (surrounds element 31 in figure 3), a distal portion (36), a proximal portion (31), a joining portion (35), means (21) for connecting the body to an auxiliary connection (luer connector shown in figure 4), wherein the main body (10) is made of a rigid material, wherein the sealing portion (41), fixing portion (43), and intermediate portion (42) are made of an elastomeric material (col. 5, lines 51-53), and wherein the auxiliary connector has a axially-symmetric male element that opens the valve (figure 5) but lacks an annular sealing element on the outside of the main body. Mathieu teaches a connector element comprising a main body (12) and a sealing element (66) on the outside of the main body (12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connection element of Orr et al. by adding a sealing element

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to the outside of the main body as taught by Mathieu in order to seal the connection between the tube and the connector more effectively.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,050,978 (Orr et al.) in view of U.S. Pat. No. 4,745,950 (Mathieu) and U.S. Pat. No. 4,638,668 (Leverberg et al.). Orr et al. discloses a connection element comprising a main body (20), a fluid passage (44), a first opening (22), a second opening (31), a shut-off element (40), a fixing portion (43), an intermediate portion (42), sealing portion (41), a first operating condition (figure 3), a second operating condition (figure 5), wherein the intermediate portion (42) deforms symmetrically (figure 4), wherein the sealing portion (41) is positioned level or flush with the leading edge (figure 3) that is slightly curved, a fluid channel (35), an outer body (23), a core (30), a tubular expansion (surrounds element 31 in figure 3), a distal portion (36), a proximal portion (31), a joining portion (35), means (21) for connecting the body to an auxiliary connection (luer connector shown in figure 4), wherein the main body (10) is made of a rigid material, wherein the sealing portion (41), fixing portion (43), and intermediate portion (42) are made of an elastomeric material (col. 5, lines 51-53), and wherein the auxiliary connector has a axially-symmetric male element that opens the valve (figure 5) but lacks an annular sealing element on the outside of the main body at the distal end and a second annular seal spaced a distance from the distal end. Mathieu teaches a connector element comprising a main body (12) and an annular sealing element (66) on the outside of the main body (12). Leverberg et al. teach a connector comprising a main body (2) and an annular sealing element (24) at a distance from the distal end (near element 29 in figure 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connection element of Orr et al. by

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incorporating an annular seal at the distal end as taught by Mathieu and an annular seal spaced from the distal end as taught by Leverberg et al. in order to seal the connection between the tube and the connector more effectively.

*Allowable Subject Matter*

8. Claims 4, 5, 12-14, and 21-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

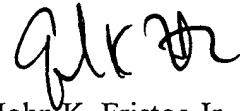
9. Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims as well as overcoming the drawing objection stated above.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John K. Fristoe Jr. whose telephone number is (571) 272-4926. The examiner can normally be reached on Monday-Friday, 7: 00 a.m-4: 30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine R. Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John K. Fristoe Jr.  
Examiner  
Art Unit 3751

JKF



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8/4/06